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10/552,366	10/03/2005	Faramarz Jadidi	HBE0012US	8303

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EXAMINER	
SZMAL, BRIAN SCOTT	
ART UNIT	**PAPER NUMBER**
3736	

NOTIFICATION DATE	DELIVERY MODE
08/27/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/552,366	JADIDI, FARAMARZ	
	Examiner	Art Unit	
	Brian Szmal	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *52 and 56-84* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *52 and 56-84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 October 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 17, 2009 has been entered.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the use of up to the sixth harmonic frequency, as claimed in Claim 84, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering

of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claim 74 is objected to because of the following informalities: "said essentially maximal muscle activity" lacks antecedent basis. Appropriate correction is required.

4. Claim 75 is objected to because of the following informalities: "a particular undesired activity" appears it should read as "bruxism". Appropriate correction is required.

5. Claims 81 and 82 are objected to because of the following informalities: "the means for frequency pattern recognition" and "the stored frequency pattern" lack antecedent basis in both claims. Appropriate correction is required.

6. Claims 83 and 84 are objected to because of the following informalities: "the stored frequency pattern" lacks antecedent basis in both claims. Appropriate correction is required.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 68 and 69 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 68 claims the step using the registered muscle activities to calculate a threshold for the feedback signal. The claim does not disclose the use of any structure, either explicit or implicit, for carrying out the method step. Furthermore, this method step can also be performed using a human to determine the threshold value. Therefore, Claim 68 fails to meet the requirements of In re Bilski, 88 USPQ2d 1385 (Fed. Cir. 2008).

Claim Rejections - 35 USC § 112

8. The following is a quotation of the sixth paragraph of 35 U.S.C. 112:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claim element “means for processing of said signals in order to detect bruxism”, in Claim 52, is a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to disclose the corresponding structure, material, or acts for the claimed function. The specification discloses the use

of a processor that is programmed to perform the processing of the signals to detect bruxism. However, the specification does not disclose any specific algorithm in detail that is used to modify a standard processor to perform the claimed functions.

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it expressly recites what structure, material, or acts perform the claimed function without introducing any new matter (35 U.S.C. 132(a)).

If applicant is of the opinion that the written description of the specification already implicitly or inherently discloses the corresponding structure, material, or acts so that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function, applicant is required to clarify the record by either:

(a) Amending the written description of the specification such that it expressly recites the corresponding structure, material, or acts for performing the claimed function and clearly links or associates the structure, material, or acts to the claimed function, without introducing any new matter (35 U.S.C. 132(a)); or

(b) Stating on the record what the corresponding structure, material, or acts, which are implicitly or inherently set forth in the written description of the specification, perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

12. Claim element "means for pattern recognition", as claimed in Claim 58, is a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to disclose the corresponding structure, material, or acts for the claimed function. The specification discloses the "means for pattern recognition" using FFT. However FFT is apparently a software-based function, and therefore does not comprise any structure.

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it expressly recites what structure, material, or acts perform the claimed function without introducing any new matter (35 U.S.C. 132(a)).

If applicant is of the opinion that the written description of the specification already implicitly or inherently discloses the corresponding structure, material, or acts so that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function, applicant is required to clarify the record by either:

(a) Amending the written description of the specification such that it expressly recites the corresponding structure, material, or acts for performing the claimed function and clearly links or associates the structure, material, or acts to the claimed function, without introducing any new matter (35 U.S.C. 132(a)); or

(b) Stating on the record what the corresponding structure, material, or acts, which are implicitly or inherently set forth in the written description of the specification,

perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

13. Claim element "means for performing a FFT analysis of said signals", as claimed in Claim 75, is a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to disclose the corresponding structure, material, or acts for the claimed function. The specification does not disclose if the FFT analysis is performed using a computer program or if the FFT analysis is performed using specific circuitry.

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it expressly recites what structure, material, or acts perform the claimed function without introducing any new matter (35 U.S.C. 132(a)).

If applicant is of the opinion that the written description of the specification already implicitly or inherently discloses the corresponding structure, material, or acts so that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function, applicant is required to clarify the record by either:

(a) Amending the written description of the specification such that it expressly recites the corresponding structure, material, or acts for performing the claimed function and clearly links or associates the structure, material, or acts to the claimed function, without introducing any new matter (35 U.S.C. 132(a)); or

(b) Stating on the record what the corresponding structure, material, or acts, which are implicitly or inherently set forth in the written description of the specification, perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

14. Claim element "means for frequency patter recognition of said signals", as claimed in Claim 76, is a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to disclose the corresponding structure, material, or acts for the claimed function. The specification does not disclose if the frequency pattern recognition is performed using circuitry or if the pattern recognition is performed using software.

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it expressly recites what structure, material, or acts perform the claimed function without introducing any new matter (35 U.S.C. 132(a)).

If applicant is of the opinion that the written description of the specification already implicitly or inherently discloses the corresponding structure, material, or acts so that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function, applicant is required to clarify the record by either:

(a) Amending the written description of the specification such that it expressly recites the corresponding structure, material, or acts for performing the claimed function

and clearly links or associates the structure, material, or acts to the claimed function, without introducing any new matter (35 U.S.C. 132(a)); or

(b) Stating on the record what the corresponding structure, material, or acts, which are implicitly or inherently set forth in the written description of the specification, perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

15. Claim element "means for determining the amplitude of the frequency content of said signals", as claimed in Claim 77, is a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to disclose the corresponding structure, material, or acts for the claimed function. The specification does not disclose if the determination of the amplitude of the frequency content of the signals is performed using circuitry or through the use of software.

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it expressly recites what structure, material, or acts perform the claimed function without introducing any new matter (35 U.S.C. 132(a)).

If applicant is of the opinion that the written description of the specification already implicitly or inherently discloses the corresponding structure, material, or acts so that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function, applicant is required to clarify the record by either:

(a) Amending the written description of the specification such that it expressly recites the corresponding structure, material, or acts for performing the claimed function and clearly links or associates the structure, material, or acts to the claimed function, without introducing any new matter (35 U.S.C. 132(a)); or

(b) Stating on the record what the corresponding structure, material, or acts, which are implicitly or inherently set forth in the written description of the specification, perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

16. Claim element "means for low-pass filtering", as claimed in Claim 78, is a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to disclose the corresponding structure, material, or acts for the claimed function. The specification does not disclose if the filtering is performed using circuitry or if the filtering is performed using software.

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it expressly recites what structure, material, or acts perform the claimed function without introducing any new matter (35 U.S.C. 132(a)).

If applicant is of the opinion that the written description of the specification already implicitly or inherently discloses the corresponding structure, material, or acts so

that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function, applicant is required to clarify the record by either:

(a) Amending the written description of the specification such that it expressly recites the corresponding structure, material, or acts for performing the claimed function and clearly links or associates the structure, material, or acts to the claimed function, without introducing any new matter (35 U.S.C. 132(a)); or

(b) Stating on the record what the corresponding structure, material, or acts, which are implicitly or inherently set forth in the written description of the specification, perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

17. Claim element "means for averaging and rectifying said signals", as claimed in Claim 79, is a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to disclose the corresponding structure, material, or acts for the claimed function. The specification does not disclose if the averaging and rectifying is performed using circuitry or through the use of software.

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it expressly recites what structure, material, or acts perform the claimed function without introducing any new matter (35 U.S.C. 132(a)).

If applicant is of the opinion that the written description of the specification already implicitly or inherently discloses the corresponding structure, material, or acts so that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function, applicant is required to clarify the record by either:

(a) Amending the written description of the specification such that it expressly recites the corresponding structure, material, or acts for performing the claimed function and clearly links or associates the structure, material, or acts to the claimed function, without introducing any new matter (35 U.S.C. 132(a)); or

(b) Stating on the record what the corresponding structure, material, or acts, which are implicitly or inherently set forth in the written description of the specification, perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

18. Claim element "means for determining and storing the frequency pattern", as claimed in Claim 80, is a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to disclose the corresponding structure, material, or acts for the claimed function. The specification does not disclose if the determination of the frequency pattern is performed using circuitry or through the use of software.

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it expressly recites what structure, material, or acts perform the claimed function without introducing any new matter (35 U.S.C. 132(a)).

If applicant is of the opinion that the written description of the specification already implicitly or inherently discloses the corresponding structure, material, or acts so that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function, applicant is required to clarify the record by either:

(a) Amending the written description of the specification such that it expressly recites the corresponding structure, material, or acts for performing the claimed function and clearly links or associates the structure, material, or acts to the claimed function, without introducing any new matter (35 U.S.C. 132(a)); or

(b) Stating on the record what the corresponding structure, material, or acts, which are implicitly or inherently set forth in the written description of the specification, perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

19. Claim element “means for comparing the frequency content”, as claimed in Claim 81, is a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to disclose the corresponding structure, material, or acts for the claimed function. The specification does not disclose if the comparison is performed using circuitry or through the use of software.

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it expressly recites what structure, material, or acts perform the claimed function without introducing any new matter (35 U.S.C. 132(a)).

If applicant is of the opinion that the written description of the specification already implicitly or inherently discloses the corresponding structure, material, or acts so that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function, applicant is required to clarify the record by either:

(a) Amending the written description of the specification such that it expressly recites the corresponding structure, material, or acts for performing the claimed function and clearly links or associates the structure, material, or acts to the claimed function, without introducing any new matter (35 U.S.C. 132(a)); or

(b) Stating on the record what the corresponding structure, material, or acts, which are implicitly or inherently set forth in the written description of the specification, perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

20. Claim element “means for comparing one or more harmonic frequencies”, As claimed in Claim 82, is a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to disclose the corresponding structure, material, or acts for the claimed function. The specification

does not disclose if the comparison is performed using circuitry or through the use of software.

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it expressly recites what structure, material, or acts perform the claimed function without introducing any new matter (35 U.S.C. 132(a)).

If applicant is of the opinion that the written description of the specification already implicitly or inherently discloses the corresponding structure, material, or acts so that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function, applicant is required to clarify the record by either:

(a) Amending the written description of the specification such that it expressly recites the corresponding structure, material, or acts for performing the claimed function and clearly links or associates the structure, material, or acts to the claimed function, without introducing any new matter (35 U.S.C. 132(a)); or

(b) Stating on the record what the corresponding structure, material, or acts, which are implicitly or inherently set forth in the written description of the specification, perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

21. Claims 52, 58, 56-67 and 69-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 52 is rejected under the basis of a lack of a specific algorithm for processing signals to detect bruxism. For example, merely referencing to a general purpose processor with appropriate programming without providing any detailed explanation of the appropriate programming, or simply reciting software without providing some detail about the means to accomplish the function, is not an adequate disclosure of the corresponding structure to satisfy the requirements of 35 USC 112, second paragraph, even when one of ordinary skill in the art is capable of writing the software to convert a general purpose processor to a special purpose processor to perform the claimed function.

Claims 58 and 75-82 are rejected under the basis of a lack of a specific structure for performing the claimed functions. The specification does not clearly disclose if the claimed functions are performed using specific hardware or software algorithms. If the claimed functions are performed by a specific algorithm to modify a standard processor, the specification also fails to disclose the specific algorithm in detail.

Claims 69 and 70 are rejected because of "preferably based on measurements of muscle activity". It is unclear to the Examiner how the threshold value would be calculated with any other measurement. Based on the current claim language, the claim can be interpreted as determining the threshold value based on other types of measurements, while the specification only discloses the use of measuring muscle

activity via EMG to determine the threshold value. Therefore the current claim is indefinite.

Claim 80 is also rejected since it is unclear to the Examiner if the "means for determining" is different from the previously claimed "means for processing of said signals".

22. Claims 52, 56-67 and 69-84 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

With regards to Claim 52, the specification fails to disclose any specific program or algorithm for performing the process of processing the signals to detect the presence of bruxism. Therefore the current specification fails to enable one of ordinary skill in the art to make or use the invention.

With regards to Claims 75-82, the specification fails to specifically disclose any specific structure or software for performing the claimed functions. The claimed functions can be performed using either a specific processing structure, or through the use of software. For instance, in Claims 78 and 79, the filtering and averaging and rectifying can be performed using a physical filter or through the use of a software-based filter, and the averaging and rectifying can be performed using a specific circuit or through the use of software. If software is utilized to perform the claimed functions, the

specification fails to provide any disclosure of a specific algorithm that would allow a general processor to perform the claimed functions.

With regards to Claims 69 and 70, the specification fails to disclose any other means for determining the threshold value with any other measurement other than muscle activity. Based on the current claim language, the claim can be interpreted as determining the threshold value based on other types of measurements, while the specification only discloses the use of measuring muscle activity via EMG to determine the threshold value.

23. Claims 69 and 70 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The current claims disclose calculating a threshold value that is "preferably based on measurements of muscle activity". Based on the current claim language, the claim can be interpreted as determining the threshold value based on other types of measurements. However the current specification fails to support any other type of measurement to determine the threshold value other than measuring muscle activity through EMG.

Claim Rejections - 35 USC § 102

24. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

25. Claims 52, 56-59, 62, 63, 65, 67-70, 72 and 76-79 are rejected under 35 U.S.C. 102(b) as being anticipated by Ober (4,669,477).

Ober discloses a means for preventing bruxism and further discloses a means for providing signals indicative of muscle activity (20); means for processing the signals in order to detect bruxism (26); means for providing a feedback signal (16, 48); wherein the apparatus is designed to be operated in a set-up mode and a use-mode (Column 3, lines 8-12, indicate the threshold can be adjusted via threshold control 32 to provide a desired predetermined level of jaw activity; this also indicates the device is setup prior to actual use); wherein the device is designed to be individually adaptable in the set-up mode, wherein a normally occurring muscle activity and a maximal muscle activity are measured and registered and used to calculate a threshold value for outputting the feedback signal, whereby criteria is established for releasing a feedback to the user in such a manner the criteria is adapted to the user (Column 3, lines 8-12, again indicates the setup of the device for the user; each device would be individually setup to each person); means for registering and storing (50) the signals indicative of muscle activity during a time interval; the apparatus is adaptable by having means for adjusting the intensity of the feedback signal (32); means for processing of the signals in order to detect bruxism comprises means for pattern recognition (26) (the signal processing circuitry would inherently include a means for recognizing the EMG pattern); one or more electrodes (20) for sensing EMG signals; the means for providing signals

indicative of muscle activity comprises other electrodes (EMG electrodes); the apparatus comprises means for storing data (50) corresponding to the measured or processed signals (the recorder can be directly connected to the signal processor for recording of the data); a user module for wearing on the head (see Figure 3); a display for displaying results from a monitoring session (the recorded information is used by a physician to determine the progress of the patient; the recorded information would inherently require a display in order for the physician to read the recorded information); providing signals indicative of muscle activity (via electrodes 20); processing the signals to detect bruxism (via signal processing circuitry 26); providing feedback (via stimulator circuit 16 and electrodes 48); during a set-up mode, measuring and registering normally occurring activity and a maximal muscle activity, and using the muscle activities to calculate a threshold value for outputting the feedback signal whereby a criteria is established for releasing a feedback to the user in such a manner that the criteria is adapted to the user (Column 3, lines 8-12, indicate the threshold can be adjusted via threshold control 32 to provide a desired predetermined level of jaw activity; this also indicates the device is setup prior to actual use and each device would be individually setup to each person); the threshold value is calculated automatically based on the EMG measurements (since the threshold value can be adjusted by a person, the threshold is calculated automatically by the person based on the acquired EMG signals); the threshold value is retrieved from a memory (the acquired signals are compared to the threshold value, therefore requiring a memory for storing the threshold value); means for pattern recognition of the signals (the signal processing circuitry

comprises means for pattern recognition); means for determining the amplitude of the signals (the signal processing circuitry comprises means for determining the amplitude of the signal); low-pass filtering of the signals (the signal processing circuitry comprises filters, including low-pass filters); and means for averaging and rectifying the signals (the signal processing circuitry comprises rectifiers and other circuits for processing signals). See also Column 2, lines 30-68; Column 3, lines 1-29 and 60-68; and Column 4, lines 1-4.

Claim Rejections - 35 USC § 103

26. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

27. Claims 52, 56-59, 62-65, 67-70, 72, 77, 78 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weinstein et al (6,270,466 B1) in view of Ober (4,669,477).

Weinstein et al disclose a means for providing biofeedback for treating bruxism and further disclose means for providing signals indicative of muscle activity; means for processing the signals to detect bruxism; means for providing feedback; the apparatus comprises means for registering and storing the signals indicative of muscle activity; the apparatus is adaptable by having means for adjusting the intensity of the feedback signal; EMG electrodes; means for providing signals indicative of muscle activity

comprises other electrodes (EMG electrodes); the apparatus comprises means for storing data corresponding to the measured or processed signals; a computer and means for transferring data thereto; a user module for wearing on the head (see Figure 2); a display (D, 102) for displaying results from a monitoring session; the threshold value is stored in a memory; means for determining the amplitude of the frequency content of the signals; low-pass filtering of the signals; and accumulating data of muscle activity and means for determining and storing the frequency pattern of the muscle activity.

Weinstein et al however do not disclose a setup mode and a use mode; the device is adaptable in the setup mode wherein normal muscle activity and maximal muscle activity are measured and registered and used to calculate a threshold value for outputting the feedback signal, whereby criteria is established fro releasing a feedback to the user in such a manner that the criteria is adapted to the user; and the threshold value is calculated automatically based on EMG measurements.

Ober, as discussed above, disclose a means of treating bruxism and further discloses a setup mode and a use mode; the device is adaptable in the setup mode wherein normal muscle activity and maximal muscle activity are measured and registered and used to calculate a threshold value for outputting the feedback signal, whereby criteria is established for releasing a feedback to the user in such a manner that the criteria is adapted to the user; and the threshold value is calculated automatically based on EMG measurements. Column 3, lines 8-12, indicate the threshold can be adjusted via threshold control 32 to provide a desired predetermined

level of jaw activity. This also indicates the device is setup prior to actual use and each device would be individually setup to each person.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Weinstein et al to include the use of a setup mode and a use mode, as per the teachings of Ober, since it would provide a means of customizing the device to individual users to prevent bruxism during sleep. It also would have been obvious to one of ordinary skill in the art to have a person monitoring the EMG signals calculate the threshold necessary to prevent bruxism and adjust the threshold, per the teachings of Ober.

28. Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weinstein et al (6,270,466 B1) and Ober (4,669,477) as applied to claim 52 above, and further in view of Junker et al (6,636,763 B1).

Weinstein et al and Ober, as discussed above, discloses a means for preventing bruxism but fail to disclose the use of a means of obtaining EEG signals.

Junker et al disclose a brain-body actuated system and further disclose the use of acquiring EEG signals. See Column 3, lines 25-33.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Weinstein et al and Ober to include the use of EEG, since it is well known in the art that EEG signals can be used to indicate muscle movement.

29. Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weinstein et al (6,270,466 B1), Ober (4,669,477) and Junker et al (6,636,763 B1) as applied to claim 60 above, and further in view of Stice (4,993,423).

Weinstein et al, Ober and Junker et al, as discussed above, disclose a means of obtaining muscle activity signals but fail to disclose a means for testing the electrodes to determine if the electrodes are connected to the skin properly.

Stice discloses a means for differential lead impedance comparison and further discloses a means for testing the electrodes to determine if the electrodes are connected to the skin properly. See Column 2, lines 64-66.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Weinstein et al, Ober and Junker et al to include the ability of determining if the electrodes are contacting the skin, as per the teachings of Stice, since it is well known in the art to utilize a means of determining the contact of the electrodes since it provides a means of accurately acquiring bioelectrical signals from the patient.

30. Claim 66 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weinstein et al (6,270,466 B1) and Ober (4,669,477) as applied to claim 52 above, and further in view of Sunouchi et al (5,368,043).

Weinstein et al and Ober, as discussed above, disclose a means for preventing bruxism, but fail to disclose the apparatus comprises a slave module and a master module, the slave module being designed for wearing by a patient.

Sunouchi et al disclose a means for measuring muscle activity and further disclose the apparatus comprises a slave module and a master module, the slave module being designed for wearing by a patient (the patient unit acquires data and transmits the data to the CPU 20 for processing and display; therefore the patient unit is the slave unit and the CPU is the master unit). See Column 6, lines 65-68; and Column 9, lines 18-27.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Ober to include the use of a computer, as per the teachings of Sunouchi et al, since it would provide an external processing means to process the data and control the feedback means.

31. Claims 71, 73 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weinstein et al (6,270,466 B1) and Ober (4,669,477) as applied to claim 52 above, and further in view of Lavigne et al (Sleep Bruxism: Validity of Clinical Research…1995).

Weinstein et al and Ober, as discussed above, disclose a means for acquiring EMG signals, processing the signals to determine the presence of bruxism and providing feedback based on the acquired signals and the threshold, but fail to disclose the threshold value is 20% of the maximal muscle activity; the normally occurring muscle activity is one or more grimaces performed by the user; and the maximal muscle activity is maximal jaw clenching performed by the user.

Lavigne et al disclose a means for monitoring for the presence of bruxism and further disclose the threshold value is 20% of the maximal muscle activity (p 548,

second paragraph); the normally occurring muscle activity is one or more grimaces performed by the user (p 547, second column, second paragraph; the "rhythmic contractions" encompass a grimace); and the maximal muscle activity is maximal jaw clenching performed by the user (p. 547, second column, second paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Weinstein et al and Ober to include a threshold value of 20% of the maximal muscle activity, grimaces and maximal jaw clenching for setting up the apparatus, as per the teachings of Lavigne et al, since it would provide a computer based means for calculating the threshold value and providing a feedback to the user for preventing bruxism.

32. Claim 75 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weinstein et al (6,270,466 B1) and Ober (4,669,477) as applied to claim 52 above, and further in view of Prass (6,306,100 B1).

Weinstein et al and Ober, as discussed above, disclose a means for treating bruxism, but fail to teach the stored signals indicative of muscle activity are processed by FFT analysis.

Prass discloses a means for neurophysiological monitoring and further disclose the stored signals indicative of muscle activity are processed by FFT analysis. See Column 37, lines 52-59.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Weinstein et al and Ober, to include the use of FFT analysis on the stored EMG signals, as per the teachings of Prass, since

it would provide a means for performing frequency analysis on the acquired EMG signals.

33. Claims 76 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weinstein et al (6,270,466 B1) and Ober (4,669,477) as applied to claim 52 above, and further in view of Massicotte et al (2004/0068196 A1).

Weinstein et al and Ober, as discussed above, disclose a means for treating bruxism using acquired EMG signals and providing feedback based on the acquired signals, but fail to disclose means for frequency pattern recognition of the signals; and means for comparing the frequency content of the signals to the stored frequency pattern.

Massicotte et al disclose a means for trend detection in a monitoring signal and further disclose means for frequency pattern recognition of the signals; and means for comparing the frequency content of the signals to the stored frequency pattern. See Paragraph 0057.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Weinstein et al and Ober to include the use of frequency pattern recognition and comparing the frequency content of the acquired signals to the stored signals, as per the teachings of Massicotte et al, since it would provide a computer based means to recognize specific signals indicating a bruxism event, such that the user can be provided feedback to arrest the bruxism event.

34. Claims 82 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weinstein et al (6,270,466 B1) and Ober (4,669,477) as applied to claim 52 above, and further in view of Hine et al (5,877,444).

Weinstein et al and Ober, as discussed above, disclose a means for treating bruxism using acquired EMG signals and providing feedback based on the acquired signals, but fail to disclose means for comparing one or more harmonic frequencies of the signals to the stored frequency pattern; and the first harmonic frequency (fundamental frequency) is compared to the stored frequency pattern.

Hine et al disclose a tuner for instruments and further disclose means for comparing one or more harmonic frequencies of the signals to the stored frequency pattern; and the first harmonic frequency (fundamental frequency) is compared to the stored frequency pattern. See Column 2, lines 46-53.

Even though Hine et al discloses a means for tuning instruments, Hine et al demonstrates that it is well known to acquire the first harmonic frequency of a signal and compare it to a stored frequency pattern to provide a diagnosis. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Weinstein et al and Ober to include comparing the first harmonic frequency of the acquired signal to a stored frequency pattern, as per the teachings of Hine et al, since it would provide a means of accurately providing feedback to a user suffering from bruxism.

35. Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ober (4,669,477) as applied to claim 52 above, and further in view of Junker et al (6,636,763 B1).

Ober, as discussed above, discloses a means for preventing bruxism but fail to disclose the use of a means of obtaining EEG signals.

Junker et al disclose a brain-body actuated system and further disclose the use of acquiring EEG signals. See Column 3, lines 25-33.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Ober to include the use of EEG, since it is well known in the art that EEG signals can be used to indicate muscle movement.

36. Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ober (4,669,477) and Junker et al (6,636,763 B1) as applied to claim 60 above, and further in view of Stice (4,993,423).

Ober and Junker et al, as discussed above, disclose a means of obtaining muscle activity signals but fail to disclose a means for testing the electrodes to determine if the electrodes are connected to the skin properly.

Stice discloses a means for differential lead impedance comparison and further discloses a means for testing the electrodes to determine if the electrodes are connected to the skin properly. See Column 2, lines 64-66.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Ober and Junker et al to include the ability of determining if the electrodes are contacting the skin, as per the teachings of

Stice, since it is well known in the art to utilize a means of determining the contact of the electrodes since it provides a means of accurately acquiring bioelectrical signals from the patient.

37. Claims 64 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ober (4,669,477) as applied to claim 52 above, and further in view of Sunouchi et al (5,368,043).

Ober, as discussed above, disclose a means for preventing bruxism, but fail to disclose a computer and a means for transferring data thereto; and the apparatus comprises a slave module and a master module, the slave module being designed for wearing by a patient.

Sunouchi et al disclose a means for measuring muscle activity and further disclose a computer and a means for transferring data thereto; and the apparatus comprises a slave module and a master module, the slave module being designed for wearing by a patient (the patient unit acquires data and transmits the data to the CPU 20 for processing and display; therefore the patient unit is the slave unit and the CPU is the master unit). See Column 6, lines 65-68; and Column 9, lines 18-27.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Ober to include the use of a computer, as per the teachings of Sunouchi et al, since it would provide an external processing means to process the data and control the feedback means.

38. Claims 71, 73 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ober (4,669,477) as applied to claim 52 above, and further in view of Lavigne et al (Sleep Bruxism: Validity of Clinical Research…1995).

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to modify the means of Ober to include comparing the first harmonic frequency of the acquired signal to a stored frequency pattern, as per the teachings of Hine et al, since it would provide a means of accurately providing feedback to a user suffering from bruxism.

Response to Arguments

42. Applicant's arguments filed June 17, 2009 have been fully considered but they are not persuasive. The Applicants argue the prior art of Ober fail to teach the new claim limitations of Claims 52 and 68, in particular, the setup mode and the use mode. The Examiner respectfully disagrees. Ober teaches the adjustment of the threshold for the feedback to the user. This inherently discloses use of a setup mode. One of ordinary skill in the art would be able to ascertain from Ober that an operator would monitor the user previous to the user using the device to determine if the threshold is set properly. The monitoring of the user would also inherently encompass any muscle movement that would create signals that would cause the device to provide feedback to the user, including normal activity and jaw clenching. The adjustment of the threshold in Ober also discloses the threshold of the device is not universal for every device; therefore the device is adjustable to each individual user.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian Szmal/
Examiner, Art Unit 3736